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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,414	11/09/2006	Todd Campbell	PA1211	4776

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
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EXAMINER	
MEDWAY, SCOTT J	

ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
05/26/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/527,414	CAMPBELL, TODD	
	Examiner	Art Unit	
	SCOTT MEDWAY	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-16 and 20-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-16 and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the second Office Action based on the 10/527,414 application filed 03/11/2005. Examiner acknowledges the reply filed 04/03/2009.

Claims 1-3 and 6-16 and 18-25 are currently pending and are considered below. Claims 1, 7, 11, 12, 18, 20 and 23 have been amended.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 7-13, 15, 16 and 19-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwarz et al (U.S. Pat. 6,368,658 B1, hereinafter "Schwarz").

Regarding claims 1, 11 and 12 Schwarz discloses methods and apparatuses for the controlled delivery of at least one pharmaceutical compound, comprising an implantable medical device (col. 3, line 52) having a surface and a coating with at least two polymer layers (col. 10, lines 1-16, 57-60; col. 11, lines 37-45) where one coating incorporates at least a releasable pharmaceutical compound (col. 4, line 37) with another layer having a property affecting releasability of the compound and where the layer differs from the first layer (e.g. col. 14, lines 23-31). As to claims 11 and 12, Schwarz discloses a number of methods to form coatings (see "Examples" 1-6 of Schwartz) and a method involving implanting the device at a target site (col. 1, lines 26-

30). Schwarz discloses a variety of polymers of different molecular weights being displaced on the device, where the coatings are made from different polymers, the different polymers known to have different molecular weights (see e.g. col. 14, lines 1-12 where primer coating solution has a different molecular weight from the top-coat solution), and further disclose a number of different degradation profiles based on the type of polymer applied (see "Example 4" of Schwartz), thus Examiner interprets molecular weight to be at least one property which inherently affects the releasability of the pharmaceutical compound.

Regarding claims 2 and 3, the implants may be selected from stents including vascular, biliary and esophageal stents (col. 3, lines 51-55).

Regarding claim 7, the layer is a polymer such as polyglycolic acid (col. 14, lines 41-55).

Regarding claims 8-10, the compound may be rapamycin (col. 4, line 37), which is known to be an anti-restentoic compound and a macrolide antibiotic.

Regarding claims 13 and 15, Schwarz discloses the tubular structure may be a stent (col. 3, lines 51-55), where the stents disclosed by Schwarz are fully capable of being mechanically expanded.

Regarding claim 16, the device may be coated with collagen (col. 6, line 53), which is a known bioresorbable coating.

Regarding claim 19, the layer is a polymer such as polyglycolic acid (col. 14, lines 41-55).

Regarding claims 20-25, the compound may be rapamycin (col. 4, line 37), which is known to be an anti-restentoic compound and a macrolide antibiotic, and additionally the pharmaceutical compound may either be contained within the polymer coating or coupled thereto (col. 5, line 61 to col. 6, line 31).

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al (U.S. Pat. 6,368,658 B1).

It is noted that Schwarz does not specifically disclose the molecular weights of the polymer types used for the medical device coating to be in the range of 1 kDa to 100,000 kDa. It would have been obvious to one of ordinary skill in the art at the time of the invention to consider implementing polymer coatings having molecular weights in this range, since it has been held that where the general conditions of a claim are disclosed in the prior art (such as high molecular weight polyglycolic acid coating), discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al (U.S. Pat. 6,368,658 B1) in view of Sirhan et al (U.S. Pat. 6,858,221 B2, hereinafter "Sirhan").

Regarding claim 14, it is noted that Schwarz does not disclose the stent to be self-expanding. Sirhan discloses a device for delivering a pharmaceutical compound, comprising a stent which may be self-expanding (col. 4, line 29). It would have been obvious to one of ordinary skill in the art at the time of the invention to consider the use of a self-expanding stent, since self-expanding stents are well-known substitutions for other kinds of stents and such an improvement would yield the predictable result of allowing a stent to be expanded in a vessel with minimal effort.

Response to Arguments

6. Applicant's arguments filed 04/03/2009 have been fully considered but they are not persuasive. Regarding claims 1, 7 and 11, Schwarz discloses the layers of the implant to be for instance polymer layers (see above)., and the polymer layers are fully capable of controllable delivery of pharmaceutical agent by varying the polymer molecular weight between the coatings.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCOTT MEDWAY whose telephone number is (571) 270-3656. The examiner can normally be reached on Monday through Friday, 7:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott J. Medway/
Examiner, AU 3763
05/20/2009

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763